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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/762,491	05/09/2001	Ying Luo	A-68285/RMS/	4855

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EXAMINER

YU, MISOOK

ART UNIT	PAPER NUMBER
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1642

DATE MAILED: 01/02/2003

20

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/762,491

Applicant(s)

LUO ET AL.

Examiner

MISOOK YU, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 October 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-26 is/are pending in the application.
- 4a) Of the above claim(s) 21-24 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-20, 25 and 26 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s) _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☒ Other: Sequence alignment.

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of group I (claims 1-20, 25, and 26) in Paper No. 17 is acknowledged. The traversal is on the ground(s) that all of the groups stem from a common concept and theory, and involve related compounds and methods, therefore examination of all pending claims would not place a burden on the examiner. This is not found persuasive because of the reasons set forth at page 2 of the previous Office Action. Groups II-IV do not relate to a single general inventive concept and examination of claims belong to groups II-IV will place a burden on the examiner.

The requirement is still deemed proper and is therefore made FINAL.

Claims 21-24 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 17.

Claims 1-26 are pending and claims 1-20, 25, and 26 are examined on merits.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 3, 16, 25, and 26 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 3, and 16 recites "hybridizes under high stringency conditions," but does not recite any hybridization conditions. Since the conditions affect what will hybridize, this is indefinite. The specification at page 15 lines 1-20 does not define what is claimed for patent protection by the instant claims.

Claims 25 and 26 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: a conclusion step linking steps a) and b) of claim 25 to the purpose stated in the preamble of claim 25.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 3, 4, 6-12, 15-20, 25, and 26 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for SEQ ID NO:5 encoding for the Apo3 protein (SEQ ID NO:6) in Figure 6, does not reasonably provide enablement for any other protein. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. The specification teaches that SEQ ID NO:5 encodes the Apo3 protein (SEQ ID NO:6) with apoptotic activity (see Figure 9). The specification does not teach any method of use for any other nucleotide molecules other than encoding a protein that has apoptotic activity. The specification does not teach any other use of various claimed proteins that lack apoptotic activity. Claims 1-20 are broadly drawn to variants of nucleic acids and proteins defined in terms of the

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degree of difference in structure from SEQ ID NO:5 or 6. Claims 25 and 26 are drawn to method of screening useful compounds using nucleic acids encoding a protein with apoptotic activity. The specification does not teach the specific structures responsible for apoptosis, nor provide guidance as to what changes in the structure can be made retaining apoptotic activity. Wang, J. et al. 2000 J. Biol. Chem. 275 (1): 507-513 provide evidence that even a single amino acid change converts a potent nuclease into a protein without any nuclease activity (see Fig. 3, 4, and 5) and the single amino acid change also converts the in vivo function of the protein in an unpredictable way (see Table 1). Considering the broad scope of the claims, and the limited teachings of the specification, it is concluded that undue experimentation would be required to enable the full scope of the claims.

Priority

Applicant's claim for domestic priority under 35 U.S.C. 119(e) is acknowledged. However, the provisional applications (60/095,590, 60/095,587, and 60/099,486) upon which priority is claimed fails to provide adequate support under 35 U.S.C. 112 for claims 1-20, 25, and 26 of this application. 60/095,590 discloses Apo2, and 60/095,587 discloses Apo1. Although 60/099,486 discloses Apo3 DNA and protein encoded by the DNA, 60/099,486 does not disclose how to use the products. Note that 60/099,486 does not disclose Figure 9 of the instant application.

Claim Rejections - 35 USC § 102

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The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

Claims **1-11, 19, and 20** are rejected under 35 U.S.C. 102(e) as being anticipated by **US Pat. 6,096,539** (filing date; June 10, 1999). US Pat. 6,096,539 teaches a polynucleotide sequence, SEQ ID NO:2 (DNA) which is 99.5 % identical to the instant SEQ ID NO:5 (DNA). Note the sequence alignment. Further US Pat. 6,096,539 claims a purified polynucleotide encoding at least 80% homology to SEQ ID NO:3. Compare instant claims 1-11, 19, and 20 with claims 1-7, and 10 of US Pat. 6,096,539.

Claims **12-18, 25 and 26** are rejected under 35 U.S.C. 102(e) as being anticipated by **US Pat. 6,267,956 B1** (priority date; June 10, 1999). US Pat. 6,267,956 teaches SEQ ID NO:3 (protein) which is 99.1 % identical to the instant SEQ ID NO:6 (protein). Note the sequence alignment. Further US Pat. 6,267,956 claims a protein having at least 80% homology to SEQ ID NO:3 and also claims an assay to screen useful compounds using apoptotic activity of the protein. Compare instant claims 12-18, 25, and 26 with claims 1-5 of US Pat. 6,267,956.

Conclusion

No claim is allowed.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to MISOOK YU, Ph.D. whose telephone number is 703-308-2454. The examiner can normally be reached on 8 A.M. to 5:30 P.M., every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony C Caputa can be reached on 703-308-3995. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Misook Yu
December 20, 2002

Mary Mosher
MARY E. MOSHER
PRIMARY EXAMINER
GROUP 1800
1600